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File: PGPB

Feb 27, 2003

DOCUMENT-IDENTIFIER: US 20030039661 A1

TITLE: Methods, compositions and kits for preserving antigenicity

INVENTOR:Aja, TeresaSummary of Invention Paragraph:

[0011] In certain aspects the virus to be detected may be herpes, HIV, cytomegalovirus (CMV), hepatitis or the like.

Summary of Invention Paragraph:

[0012] In the various aspects the antigen comprises a viral antigen present on the surface of the mammalian cells. In related embodiments, the antigen comprises the pp65 protein of CMV.

Detail Description Paragraph:CMV PP65 Antigenicity EnhancementDetail Description Paragraph:

[0640] Cytomegalovirus (CMV) antigenemia assay is the method of choice for rapid quantitative diagnosis of CMV infection and monitoring antiviral therapy. Due to the rapid loss of infected neutrophils by apoptosis, specimens must be processed within 6 hr of collection. Processing after 6 hr may diminish pp65 positive cell counts, leading to potentially erroneous values and quantitative levels for the patients' risk of CMV disease.

Detail Description Paragraph:

[0641] The study objective was to determine if pp65 antigenicity of CMV infected peripheral blood leukocytes (PBLs) could be preserved by the addition of a compound of the following formula: 61

Detail Description Paragraph:

[0677] Eighteen bone marrow transplant patients with suspected active CMV infection were investigated. For each sample, a 10 mL peripheral blood specimen was split and the apoptotic inhibitor added to half the sample. The other half was used as a control. Aliquots were taken at 0 hr, 48 hr and 72 hr and enriched for PBLs by dextran separation followed by RBC lysis. Two slides were prepared by cytocentrifugation for each condition. Each slide was stained for the pp65 CMV early immediate antigen using a brightfield immunocytochemical staining method. Slides were then analyzed using the Automated Cellular Imaging System (ACIS.TM.), reviewed and the number of pp65 positive cells determined. A Wilcoxon Matched Pairs test was applied to the data.

Detail Description Paragraph:

[0679] Accordingly, apoptotic inhibitors preserve pp65--antigen positivity through 72 hr. Increasing sample stability to 72 hr results in a more robust CMV antigenemia assay adaptable to centralized laboratories and more accurate assessment of CMV active infections and disease management.

## CLAIMS:

5. The method of claim 1, wherein said virus is selected from the group consisting of herpes, HIV, cytomegalovirus (CMV), and hepatitis.
6. The method of claim 5, wherein said virus is CMV.
8. The method of claim 7, wherein said antigen comprises pp65 protein of CMV.

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